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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,219	12/03/2004	Yves Christen	427.092	2637

47888 7590 03/26/2007
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NEW YORK, NY 10036

EXAMINER

CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/517,219	Applicant(s) CHRISTEN, YVES	
	Examiner Catherine Chen	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,6 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,6 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>Dec. 3, 2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Currently, Claims 2-3, 6, 9-11 are pending and examined.

Election/Restrictions

Applicant's election without traverse of Claims 2-3, 6, 9-11 in the reply filed on Feb. 7, 2007 is acknowledged. Claims 1, 4-5, 7-8 are canceled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwabe (US 5399348).

Schwabe teaches extract from Ginkgo biloba leaves of 20-30% weight flavone glycosides, 2.5-4.5% weight of ginkgolides A, B, C, and J, 2.0-4.0% weight bilobalide, less than 10 ppm alkylphenol compounds, and less than 10% weight proanthocyanidins (column 3, lines 3-4, 10-17).

Schwabe does not specifically teach using the claimed composition to promote muscle mass to the detriment of fatty mass in warm-blooded animals. However, the composition of Schwabe is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has fat and muscle masses. Thus, on the administration of the claimed composition to any patient,

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promotion of muscle mass to the detriment of fatty mass in warm-blooded animals would have had to occur if applicant's invention function as claimed.

Claims 2, 6, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Reilly et al. (US 5389370).

O'Reilly et al. teaches Ginkgo biloba extract with 40-60% flavone glycosides, 5.5-8.0% ginkgolides A, B, C, and J, 5.0-7.0% bilobalide (column 3, lines 36-40).

O'Reilly et al. does not specifically teach using the claimed composition to promote muscle mass to the detriment of fatty mass in warm-blooded animals. However, the composition of O'Reilly et al. is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has fat and muscle masses. Thus, on the administration of the claimed composition to any patient, promotion of muscle mass to the detriment of fatty mass in warm-blooded animals would have had to occur if applicant's invention function as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-3, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwabe (US 5399348).

Schwabe teaches extract from Ginkgo bibloba leaves of 20-30% weight flavone glycosides, 2.5-4.5% weight of ginkgolides A, B, C, and J, 2.0-4.0% weight bilobalide, less than 10 ppm alkylphenol compounds, and less than 10% weight proanthocyanidins (column 3, lines 3-4, 10-17). However it does not teach the specific amount of 2% bilobalide and promotion of muscle mass to the detriment of fatty mass in warm-blooded animals.

Schwabe does not specifically teach using the claimed composition to promote muscle mass to the detriment of fatty mass in warm-blooded animals. However, the composition of Schwabe is considered to intrinsically teach the claimed method because both the reference and the claimed invention are administering the same composition. Thus, on the administration of the claimed composition, promotion of muscle mass to the detriment of fatty mass in warm-blooded animals would have had to occur if applicant's invention function as claimed.

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The reference also does not specifically teach adding the ingredient in the amount claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 2-3, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwabe (US 5399348) as applied to claims 2-3, 9-11 above, and further in view of Stankov (EP 1093817 A1).

Schwabe teaches extract from Ginkgo bibloba leaves of 20-30% weight flavone glycosides, 2.5-4.5% weight of ginkgolides A, B, C, and J, 2.0-4.0% weight bilobalide, less than 10 ppm alkylphenol compounds, and less than 10% weight proanthocyanidins (column 3, lines 3-4, 10-17). However it does not teach the specific amount of 2% bilobalide and promotion of muscle mass to the detriment of fatty mass in warm-blooded animals.

Schwabe does not specifically teach using the claimed composition to promote muscle mass to the detriment of fatty mass in warm-blooded animals. However, the composition of Schwabe is considered to intrinsically teach the claimed method because both the reference and the claimed invention are administering the same composition. Thus, on the administration of the claimed composition, promotion of muscle mass to the detriment of fatty mass in warm-blooded animals would have had to occur if applicant's invention function as claimed.

The reference also does not specifically teach adding the ingredient in the amount claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Stankov teaches weight-control diet (paragraph 0003) with extract from *Gingko biloba* containing flavonglycosides (paragraph 0011).

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The Schwabe reference does not specifically teach that the claimed ingredients in particular can be used to treat weight control. However, a person of ordinary skill in the art would reasonably expect that compounds from ginkgo biloba could be used to treat weight control based on the broad disclosure by the Stankov reference. Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to use the claimed ingredients to treat weight control.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-3, 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7138148 B2. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because US'148 claims a method for treating sarcopenia, which is a muscle mass disease. The treatment of this disease involves the promotion of muscle mass. Therefore, there is an overlap in scope between the claimed invention and the claims of US '148.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Patent Examiner
Art Unit 1655

S Hoffman
3-18-07

SUSAN COE HOFFMAN
PRIMARY EXAMINER